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THE BENEFITS OF PATIENT PERSPECTIVES IN HEALTH TECHNOLOGY DEVELOPMENT

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Medtech Navigator

The Medtech Navigator (www.medtechnavigator.co.uk), part-funded by the European Regional Development Fund (ERDF), is a three-year programme, delivered by Health Enterprise East Ltd., to facilitate knowledge exchange between the medtech industry, many of whom are small and medium sized enterprises (SMEs), the NHS, and academia. The programme seeks to enable companies to identify potential market opportunities in a variety of specific disease areas and apply for Innovation Grant funding through the programme, thereby engaging SMEs in new R&D projects that are both customer-focused and collaborative in nature. This will allow the creation of partnerships between clinicians, academics, and industry to develop novel medical technologies which will improve healthcare and quality of life for patients and the healthcare market of the future.

Health Tech Enterprise

At Health Tech Enterprise, we believe in improving healthcare through technology and innovation. We work with the NHS, medical technology industry and government organisations to help turn innovative ideas into products and services that will benefit patients.

Our experienced team offers clients a diverse range of business and innovation management services. Our strengths include IP management, technology commercialisation, health economics and strategic market access advice.

Based in Cambridge, we work with over 20 NHS organisations nationally and medtech companies globally. Our aim is to help our clients address the challenges faced along the product development pathway, connecting them with relevant healthcare experts and funding opportunities.

1. Introduction

Creating and producing medical technologies is often a challenging process. To create successful Medical Technology innovations, they need to excel in functionality, safety, efficiency, and usability. But technical or functional excellence is not enough. Technology does not in itself improve healthcare. It needs to be used by clinicians and, in many cases, patients or their carers. So, to launch a technology that is integrated into care-management routines and well-accepted by end-users, innovators need to include user perspectives within the design process. A direct engagement with clinicians and patients provides Health Technology developers with a crucial insight into a product's design in terms of its usability, ease of use, and consumer appeal.

In developing user-friendly and desirable technology, innovators and product designers should consider a range of different aspects, such as: simplicity, attention to detail, integration into users' lifestyles, future-proof design and environmental sustainability. As well as making devices useable, User-Centric design can influence positive behaviours beyond the actual use of the device, such as adherence to treatment regimens, resulting in better health outcomes. User-centric design is proven to contribute to the shift towards patient-centred care and alleviation of some persisting issues faced by the NHS.

So, the inclusion of user insight in developing technologies often leads to improved efficiencies in healthcare systems. They, in turn, allow for freeing up the resources for other therapeutic areas and stimulate new therapy routes.

2. Towards Patient-centred Care

Recently, the NHS has pledged to involve patients (and carers) more in their care by giving them the power, in other words: enabling them, to manage their health. This means making informed decisions about their condition management and provide support to take care of their physical and mental well-being[1]. Personalised care represents a new relationship between patients, healthcare professionals, the community, and the system[1]. A growing body of qualitative and quantitative studies[2] confirm that patient-centred care tends to improve clinical outcomes, improve patient experience, as well as contributing to a reduction of resource waste within the system[3]. Successful transition to personalised care is determined by many different factors including: patient choice, shared decision-making, patient engagement and activation, supported self-management, social prescribing, and community-based support. MedTech innovations, which include medical devices as well as digital interventions, have the potential to contribute towards personalised care by allowing patients to have access to relevant information, enabling them to monitor and better manage their health conditions.

There are several needs and perspectives that innovators need to take into account when developing medical solutions. Firstly, innovators ought to account for the needs and perspectives of different stakeholders such as : the regulatory commission, medical device manufacturer, physician, and patient.[4] A collaborative design process that unifies clinicians, patients, engineers, and manufacturers can be summarised in three stages: firstly, outlining a concept to match users' needs; secondly, developing the device, engaging with user groups throughout, and thirdly, the evaluation stage, in which actual

users provide feedback to validate that the innovation meets the original users' need. The collaboration can serve to establish the right balance of technical capability, clinical efficacy, ease of use and consumer appeal[5].

3. Baseline Components for MedTech Innovations

Current Care Pathway

Before the innovation prototype development, innovators should carefully analyse the current care pathway in the region they intend to enter the market. In the United Kingdom, the current care management can be consulted with NICE guidelines or experts in the field, depending on the health condition.

The current care pathways are often heterogeneous both across patient groups and hospitals. According to Fabian Joeres, usability engineer and UX researcher in the medical field, "medical processes are a lot less standardised than we (e.g. patients) imagine. Especially for clinicians, the mindset is very much shaped by the way they have been trained, and hospitals they have worked for. Thus, broadening the perspective is extremely important so that the innovation is applicable not only for [their] hospital but for the wider healthcare market."[15] To understand the wider clinical context and grasp roles in the medical processes, innovators should visit different healthcare institutions, and interact with clinicians from different clinical settings.

Besides, clinical practice, the developers have to consider how the innovation will impact the current care pathway and user's and carer's routines, and the possible consequences of the changes. The value of routine should not be underestimated either. Technologies that disrupt daily routines, especially those for which the patient has responsibility, tend to fail unless they can be easily integrated into a user's day-to-day routine. Building technology around the user's standard practices helps to remove barriers to adoption.

Device Users Vary

Many patient-use medical devices have user groups. These user groups can be variable, depending on the type of innovation. Joeres emphasises that a good understanding of the innovation's users is the first step in developing a product.[15] The end users of medical technology can be patients, parents and loved ones, administrators, and healthcare professionals (doctors and nurses)[6]. MedTech innovations often have primary and secondary users, and they may have competing priorities regarding the technology.

Identifying relevant characteristics and heterogeneity among technology users is equally important. Whereas some homogeneity in terms of skills and technical abilities is likely to exist among healthcare professionals, patients and carers are highly heterogeneous in terms of physical characteristics, i.e., size, strength, stamina, dexterity, and coordination, as well as varying greatly in insight, willingness and ability to engage with the device. It is also crucial to account for sensory (vision, audition), cognitive abilities (such as

memory), and levels of digital and technical capabilities among the target end-user group to develop a successful design of an innovation[6].

Acquiring patient perspectives may uncover unforeseen challenges. For instance, an elderly user group might struggle with new technology adoption, which can cause issues should the technology require self-monitoring or patient input. Gaining insight before finishing and releasing the product may prevent commercial failures.

Developing technology for children and young adults requires particular attention. Too often, it is assumed that a product primarily designed for adults, simply need to be downsized for use by children and young people. However, their psychological, social, and emotional characteristics are very different from adults. Thus, ignoring their specific needs and capabilities would lead to ineffective solutions, that would not be adopted. For example, an innovative technology which is focused on voice recognition for usability can be easily programmed for adults. But when considering a child patient, especially boys, whose voice is likely to deepen, change and break over time, additional layers of adaptability to the user, and perhaps by the patient are required. Medical technology solutions for children, particularly those designed for long-term usage, need to be adaptable to the patient as the user grows and changes.

Similar issues arise when designing for older people. On the one hand, it is often assumed that older people will not be familiar with recent technology, an assumption that is rapidly becoming obsolete. At the same time, the easy with which younger people re able to adapt to new technology may not be as easy for use by others, who have not been exposed to, or are less familiar with the latest tech.

Use Environment

The use environment is a second essential component to identify in developing medical technology. The device's design is highly dependent on environmental or location conditions. The device’s interface has different requirements, depending on whether it is used in clinical, home, or outside settings[6]. Differences may appear even within each environmental category: for instance, clinical settings can be A&E, ICU, point of care, laboratory, bedside, or others. If a device is designed for use in the home environment, the developer has to consider the setup and technical support aspects of the device. If the technology is used outside (that mostly applies to wearable devices), external environments, such as humidity, temperature, and motion levels have to be accounted for. Other aspects, such as noise levels and lighting conditions are important in developing useable and user-friendly devices[6]. Conducting appropriate useability, or Human Factor, studies, covering each of these conditions, can help identify any problems, and enable the developer to re-design the product in order to mitigate these.

User Interface

The user interface covers all points of interaction between the product and the user, including elements such as displays, controls, packing product labels and instructions for use. Important aspects of the user interface include the product’s shape and size and

user-system interaction. The considerations should also include connection to the internet (if required), power requirements, and mobility or portability of a device.

4. Ways of Collecting Insights

Some ways to collect user insight include surveys, interviews, iterative testing, and immersive research. Whereas surveys and interviews tend to be cheaper and quicker options to collect and gain user perspectives, iterative testing and immersive research can prove to be very beneficial. Iterative testing is a research method where a product is tested on users repeatedly. It helps to identify issues at early stages via user feedback. The process helps to minimise issues in the early stages and ensure a user-led design. In addition to enhancing products' usability and matching user needs, iterative usability studies aim to capture and reduce the risk of inappropriate use, thus, improving the safety and effectiveness of innovations.

Immersive research is a research methodology that allows one to gain direct insight into the user's experience with medical technology. Typically, researchers shadow users engaging with innovations for a few days. The immersion in the user experience allows developers to understand the context, define user requirements, and identify ways to improve the product. This research method provides valuable feedback since users' actions tend to reveal insights about the product that may not be uncovered in an interview. However, immersive research may be difficult to conduct, especially if a medical innovation is used in non-clinical settings.

User-insight research approaches and implementation strategies will be different for each type of device or design. They should be primarily determined by the innovation type, development stage, and target markets. For instance, user-insight research execution for digital technologies and technological devices is different in terms of the frequency of prototype testing. The nature of digital technologies allows for a higher number of iterative testing cycles and therefore enables greater interaction between end-users and developers.[15]

Human factor engineering expertise is very valuable in developing a suitable conceptual approach, identifying relevant research questions at each development stage, and defining more fine-grained aspects, such as method choice and question types. Seeking advice and insights from experts in this field helps to maximise the value of the user experience research and avoid potential pitfalls.[15]

5. Successful Examples

Engagement with Young People

Planning for the new Cambridge Children's Hospital includes is a promising hospital project that aims to deliver patient-centred services through active engagement with

patients and their carers. Cambridge Children's Network, made up of children, young people, parents, and carers, provides insight into a first-hand experience of being in hospital or using mental health services all over the East of England. Cambridge Children's Hospital plans a comprehensive integration of patient perspectives in the children's hospital services and facilities, which is expected to bring about better children's experience and health outcomes[7].

Similar to this, GenerationR[8] links healthcare services to a national network of Young People's Advisory Groups (YPAGs) based across the UK. GenerationR YPAGs are predominantly made up of 10 to 15 members aged between 8 and 19, and their views feed into the design and delivery of MedTech for children and young people via the hospitals at which they might receive treatment. The input of these young people and the access to their perspective in the design process shape crucial changes to newly developed technologies.

BFB Labs specialises in digital therapeutics for better youth mental health. Lumi Nova[9] is a digital therapy game designed to help children and young people with anxiety.[10] Throughout the game, young people encounter challenges and try out situations they find difficult in life and rate how anxious they feel. Children and their parents played an active role in the game development process. Currently, a research study is being conducted to assess the effectiveness of the product. Throughout the study, 10 young people and their parents will actively engage through an Advisory Group by giving feedback and suggestions for the product.[10]

Currently, a team of clinicians and researchers from Sheffield Hallam University, Sheffield Children's NHS Foundation Trust and Leeds Teaching NHS Trust are developing an immersive virtual reality platform. The technology aims to help children with Duchenne muscular dystrophy (DMD) to engage in physiotherapy exercises. The research team is working closely with children, who have DMD, to develop VR games that will improve bodily movement, and motor function, decrease anxiety and improve the overall quality of life.[11]

Open Bionics[12] is another notable example of engaging with young users in developing medical technologies. Open Bionics is a UK-based company that uses an open-source approach to develop 3D-printed bionic limbs for young patients with below-elbow limb differences. Gathering insights from patients revealed that many children avoid using prosthetics due to the stigma attached and the cumbersome nature of adapting to a prosthetic. To combat this, the company worked with the NHS to improve the experience for patients and create a new bionic product that is inspirational for users. In 2015, the company even secured a licensing deal with Disney to create superhero-themed prosthetics, which further encouraged adoption by children.

Technology integration in a daily routine

Dexcom[13] and Freestyle Libre[14] are self-monitoring systems for people with Type 1 diabetes. The technologies are integrated with daily routines through mobile applications. Paired with glucose monitoring sensors, these apps enable patients and their loved ones to access their HbA1C levels instantly and thus empower patients to better self-manage their condition.

6. Challenges

Gaining effective user input comes with a few challenges. They include high recruitment costs, identifying biased and false reports, and translating users' needs into manufacturing specifics.

According to Joeres, the main challenge is the recruitment of qualified interview partners, especially when the relevant participants are from highly specialised demographics. Though highly relevant, the process tends to increase the costs of usability research. Joeres recommends starting to develop relevant networks at the early stages of innovation development.[15]

It is important to recognise that some individual users, or even whole user groups may have preconceptions about certain technologies based on their past experiences and, if such a user group is strongly motivated to give feedback, it may not represent all the users. Also, the technology may have been further developed and advances since their last experience. One way of mitigating against this issue is positive and active engagement with as wide a variety of users as possible. Involving users in product development (through iterative testing) or conducting immersive research would alleviate the issue. Relatedly, racial and social bias can significantly distort the results. Thus, it is important to ensure that insights and feedback are representative of all users, from all ethnicities, age groups, and social backgrounds.

Another challenge is the effective integration of user insights into actual engineering requirements and solutions. Interestingly, Joeres warns against overreliance on user perspectives in the product development process: "Recall that users are not designers, the users are not engineers either. Users are not supposed to present the solutions, users should identify issues and needs, and professionals have to build solutions."[15] A related challenge is bridging between 'soft' user requirements to 'hard' manufacturing specifics. Experts in human factor engineering are developing systematic approaches to effectively map patients' and other users' feedback on actual product characteristics.[15]

7. Future Opportunities

The importance and prevalence of user-centric design are expanding due to both cultural and technological aspects.[15] Recently, different stakeholders, including patients, physicians, engineers, and budget planners, have started to realise the value of the user-centric design of medical technologies. Equally, rapid technological advancements, such as sensors, AI methods, and the ever-growing influx of data, facilitate possibilities for developing personalised medical care through MedTech.[15]

Currently, there are fast growing opportunities for MedTech and digital solutions to improve the patient journey in an array of areas, e.g., asthma, diabetes, and mental health. A sufficient level of consulting with the main user base is essential to maximise the potential. When digital solutions are integrated within a younger demographic, developers need to consider how to make condition management an engaging activity. Gamification integration in self-management is a growing field.

In 2021, the World Health Organisation confirmed that the use of video games could prove useful in producing positive healthcare outcomes. Virtual Reality simulators are being increasingly applied within certain health-management areas, such as physiotherapy and rehabilitation. Gaming can act as a powerful motivator for younger patients and through gaming exercises, the end-to-end user experience will be improved. However, it is notable that a game cannot simply be designed hastily with the hope of positive outcomes and, as such, will require extensive research and user insight before the start of the development process.

8. Takeaway Message

The benefits of gathering insights from different user groups are immense: good useability research provides the necessary intelligence required to make an innovation serve its purpose and be successful. It is essential that innovators start usability research early and do it systematically to bring the most value to the future product.

As the principles and methods of user engagement are perhaps less familiar for both clinicians and product designers, seeking help and support from experts in this field can greatly maximise the opportunity to make the product development journey successful. This in turn will help meet the challenge of ever increasing needs and demand for better and more efficient, patient-centred healthcare.

9. References

[1] England, N. H. S. n.d. “NHS England » Personalised Care.” Accessed December 30, 2022. https://www.england.nhs.uk/personalisedcare/.

[2] England, N. H. S. n.d. “NHS England » Evidence and Case Studies.” Accessed January 18, 2023. https://www.england.nhs.uk/personalisedcare/evidence-and-case-studies/.

[3] England, N. H. S. n.d. “NHS England » Involving People in Their Own Care.” Accessed December 30, 2022. https://www.england.nhs.uk/ourwork/patient-participation/.

[4] Hagedorn, Thomas J., Sundar Krishnamurty, and Ian R. Grosse. 2016. “An Information Model to Support User-Centered Design of Medical Devices.” Journal of Biomedical Informatics 62 (August): 181–94.

[5] “Success Depends on Putting the Patient at the Centre of Telemedicine Interface Design.” n.d. Cambridge Consultants. Accessed December 30, 2022. https://www.cambridgeconsultants.com/insights/opinion/success-depends-putting-patient-centre-telemedicine-interface-design.

[6] “3 Critical Starting Points for Medical Device Design Usability Research.” 2022. Medical Design and Outsourcing. October 18, 2022. https://www.medicaldesignandoutsourcing.com/medical-device-design-usability-research-starting-points/.

[7] “Cambridge Children’s Network.” n.d. Cambridge Children’s. Accessed January 3, 2023. https://www.cambridgechildrens.org.uk/collaboration/childrens-network-new/.

[8] “Generation R.” n.d. Accessed January 3, 2023. https://generationr.org.uk/.

[9] “Lumi Nova: Tales of Courage —.” n.d. BfB Labs. Accessed January 12, 2023. https://www.bfb-labs.com/luminova.

[10] Labs, Bfb. 2022. “Evaluating Effectiveness and Barriers to Access for Children and Families from Ethnic Minority Groups and Those Living in Deprivation.” BfB Labs. March 16, 2022. https://www.bfb-labs.com/news/2022/3/15/evaluating-effectiveness-and-barriers-to-access-for-children-and-families-from-ethnic-minority-groups-and-those-living-in-deprivation.

[11] Johnson, Sarah. n.d. “[No Title].” Accessed January 12, 2023. https://www.duchenneuk.org/virtual-reality-trialed-to-help-children-with-dmd-engage-in-physiotherapy/.

[12] “Open Bionics - Turning Disabilities into Superpowers.” 2021. Open Bionics. May 20, 2021. https://openbionics.com/en/.

[13] “Diabetes CGM Apps for Your Phone or Smartwatch.” 2022. Dexcom. May 13, 2022. https://www.dexcom.com/en-GB/dexcom-apps.

[14] “FreeStyle Libre 2.” n.d. Accessed January 3, 2023. https://www.freestylelibre.co.uk/libre/.

[15] “User-centric Design in MedTech.” Interview with Fabian Joeres. Conducted January 17, 2023.